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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/742,803

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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1773

MAIL DATE

DELIVERY MODE

02/15/2011

PAPER

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/742,803

Applicant(s)

MCLUEN ET AL.

Examiner

DWAYNE K. HANDY

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30, 35-38, 40, 42, 44-48 and 50-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30, 35-38, 40, 42, 44-48 and 50-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 27-30, 35-38, 40, 42, 44-48 and 50-62 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-55 of copending Application No. 12/154,880. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection was applied in the previous Office Action (mailed 09/17/10). See Paragraphs 2-3. It remains in effect. Please see the comments in the "Terminal Disclaimer" section below.

Inventorship

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 27-29, 35-38, 40, 42, 44, 52 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGraw et al. (5,368,823).
6. Claims 27-29, 35, 36, 38, 45-48, 50-54, 56, 57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckermann et al. (5,240,680).
7. Claims 27-30, 35, 36, 38, 45-48 and 50-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cargill et al. (5,609,826).

These rejections were maintained in the previous Office Action (mailed 09/17/10). They remain in effect. Please see Response to Arguments below.

Terminal Disclaimer

8. The terminal disclaimer filed on 11/29/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted from Application No. 12/154,880 has been reviewed and is NOT accepted. The terminal disclaimer submitted by Applicant contains the phrase "Which would extend beyond the expiration date of the full statutory term defined in 35 USC 154 to 156 and 173.....". This is improper language because 35 USC 155 and 35 USC 156 do not define the term of the patent. The terminal disclaimer should read "35 USC 154 and 173".

Response to Arguments

9. Applicant's arguments filed 11/29/10 directed to the 102 rejections (see pages 10-13 of Applicant's Arguments submitted 11/29/10) have been fully considered and they are persuasive. The references do not teach the previously added (See Amendment with RCE on 06/04/10) limitation of the interior wall that linearly tapers from the external support to the frit. The Examiner had previously removed the 102 rejections of claim 29 in response to the addition of the limitation "wherein the interior wall linearly tapers from the exterior support to the frit". See Paragraph 1 of the Office Action mailed 03/04/10. Given that this feature has also been added to claim 27, the 102 rejection of these claims should also be removed. The Examiner apologizes for the oversight in the previous Office Action.

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10. Applicant's arguments filed 11/29/10 directed to the previous 103 rejections have been fully considered but they are not persuasive.

McGraw

11. Applicant has argued that McGraw does not teach a protruding support that extends along the entire circumference of the top opening of the vial (Page 14 of Arguments). This feature is beyond the scope of all claims except for claim 62 - as only claim 62 contains this feature. Claim 62 has not been rejected under McGraw.

12. Applicant has argued that McGraw does not teach an interior wall that provides the sole support for the frit (Page 14 of Arguments). The Examiner respectfully submits that this is beyond the scope of the claims as written. Each independent claim as written simply recites a vial comprising... "a bored interior having a consistent dimension to hold a frit". In addition, the Examiner notes that McGraw does indeed include a support (100), but Figure 6 clearly shows the frit (9) supported by the sidewalls in the tapering portion in the bottom of the vial.

13. Applicant has also argued that *In re Dailey* does not apply (Page 15 of Arguments). . Applicant has argued that the small narrowed portion of McGraw below the frit does not provide the function of retaining the solid support and frit. The Examiner respectfully disagrees. The narrow portion of McGraw holds the lower frit (9) – which holds the support (100) and upper frit (9A). See column 5, lines 52-54 and

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Figure 6. Applicant has argued that the only difference in Dailey was a matter of degree or magnitude. The Examiner submits that a difference in degree or magnitude is what McGraw teaches; rather than tapering from the top to bottom of the vial, the vial simply tapers at the bottom to a degree that is different from that of Applicant - but it still holds the frit in place. Applicant has argued that a "difference in degree" is not the same as a "difference in position", but the Examiner disagrees that the taper feature is a difference in position. The degree of tapering in McGraw is smaller (it doesn't taper from the top to bottom), but again, the taper at the bottom provides support for the support and frit of McGraw.

14. Applicant has argued that the tapered feature is significant since the tapered feature is what makes a consistent compression and seal with the frit possible (Pages 16-17 of Arguments) Applicant refers to the following passage from the Specification:

Present Specification that "[a] precision bored interior 630 holds the flit 620 in place and provides a consistent compression and seal with the flit 620. As a result of the precision bored interior 630, there is a consistent flow of reagent solution through each vial during both the dispensing and purging processes."

[Present Specification, page 14, lines 3-6]. See Arguments, page 16.

The Examiner notes, however, that this passage has nothing to do with the taper of the vial and instead is directed simply to a bored interior. Applicant has also argued that the tapered configuration is key to producing a consistent flow. The Examiner again notes that "a consistent flow" has nothing to do with retaining the frit or support in

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the vial. The issue is whether the vial having a different shape can still retain the frit. In the case of McGraw, this is what the prior art shows – a vial having a different shape but still retaining the frit.

15. Applicant has also argued that the tapered configuration is significant in that it allows substantially the entire body of the vial to fit within the cartridge. Applicant refers to the Specification (Page 14, lines 7-9) on page 17 of Arguments:

"....that "[t]he exterior of each vial 181 also has a precise dimension around the support 660. This support 660 fits within the receiving hole 185 within the cartridge 170 and provides a pressure tight seal around each vial within the cartridge 170." [Present Specification, page 14, lines 7-9] In other words, **because the tapered configuration ensures that the vial gets increasingly narrower from top to bottom, it allows the support 660 to be specifically dimensioned to form an air-tight seal with the cartridge without any of the lower portions of the vial being too large to fit within the cartridge hole.**

The Examiner submits that Applicant's Arguments are beyond the scope of this passage. The passage from the Specification cited by Applicant does not cite the tapering shape as critical to vial insertion.

16. Applicant has argued McGraw does not have a support that has a precise dimension that provides a pressure tight seal around the vial when placed in a cartridge. Applicant has also argued that McGraw does not teach a direct fit (Pages 18-26 of Arguments). The Examiner directs Applicant to Paragraph 14 of the Office Action mailed 09/18/09 which addresses this argument.

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Zuckermann

17. Applicant has argued that Zuckermann does not teach a protruding support that extends along the entire circumference of the top opening of the vial (Page 27 of Arguments). This feature is beyond the scope of all claims except for claim 62 - as only claim 62 contains this feature. Claim 62 has not been rejected under Zuckermann.

18. Applicant has also argued that *In re Dailey* does not apply. Applicant has argued that the small narrowed portion of Zuckermann below the frit does not provide the function of retaining the solid support and frit (Page 28 of Arguments). The Examiner respectfully disagrees. The narrow portion of Zuckermann holds the frit. See Figure 3. Applicant has argued that Zuckerman does not taper until below the frit. The Examiner submits that in Zuckermann, the vial simply tapers at the bottom such that the vial is a different shape than the instant vial - but it still holds the frit in place. The amount of tapering in Zuckermann is different and leads to a different vial shape, but again, the taper at the bottom provides support for the support and frit of Zuckermann.

Applicant has argued that the only difference in *Dailey* was a matter of degree or magnitude. The Examiner submits that a difference in degree or magnitude is what Zuckermann teaches; rather than tapering from the top to bottom of the vial, the vial simply tapers at the bottom to a degree that is different from that of Applicant - but it still holds the frit in place. Applicant has argued that a "difference in degree" is not the same as a "difference in position", but the Examiner disagrees that the taper feature is a difference in position. The degree of tapering in Zuckermann is smaller (it doesn't taper

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from the top to bottom), but again, the taper at the bottom provides support for the support and frit of Zuckermann.

19. Applicant has argued that the tapered feature is significant since the tapered feature is what makes a consistent compression and seal with the frit possible (pages 28-29 of Arguments). Applicant then refers to the following passage from the Specification:

Present Specification that "[a] precision bored interior 630 holds the flit 620 in place and provides a consistent compression and seal with the flit 620. As a result of the precision bored interior 630, there is a consistent flow of reagent solution through each vial during both the dispensing and purging processes."
[Present Specification, page 14, lines 3-6]. See Arguments, page 29.

The Examiner notes, however, that this passage has nothing to do with the taper of the vial and instead is directed simply to a bored interior. Applicant has also argued that the tapered configuration is key to producing a consistent flow. The Examiner again notes that "a consistent flow" has nothing to do with retaining the frit or support in the vial. The issue is whether the vial having a different shape can still retain the frit. In the case of Zuckermann, this is what the prior art shows – a vial having a different shape but still retaining the frit.

20. Applicant has also argued that the tapered configuration is significant in that it allows substantially the entire body of the vial to fit within the cartridge. Applicant refers to the Specification (Page 14, lines 7-9) on page 30 of Arguments:

"....that "[t]he exterior of each vial 181 also has a precise dimension around the support 660. This support 660 fits within the receiving hole 185 within the cartridge 170 and provides a pressure tight seal around each vial within the cartridge 170." [Present Specification, page 14, lines 7-9] In other words, **because the tapered configuration ensures that the vial gets increasingly narrower from top to bottom, it allows the support 660 to be specifically dimensioned to form an air-tight seal with the cartridge without any of the lower portions of the vial being too large to fit within the cartridge hole.**

The Examiner submits that Applicant's Arguments are beyond the scope of this passage. The passage from the Specification cited by Applicant does not cite the tapering shape as critical to vial insertion.

21. Applicant has argued Zuckermann does not have a support that has a precise dimension that provides a pressure tight seal around the vial when placed in a cartridge. Applicant has also argued that Zuckermann does not teach a direct fit (Pages 31-41 of Arguments). The Examiner directs Applicant to Paragraph 16 of the Office Action mailed 09/18/09 which addresses this argument.

Cargill

22. Applicant has argued that Cargill does not teach a protruding support that extends along the entire circumference of the top opening (Pages 42-43 of Arguments). The Examiner agrees that the protruding support of Cargill does not extend along the

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entire circumference of the top opening. The Examiner, however, takes the position that the difference is one of mere shape. Cargill teaches a vial having a protruding support with a different shape than the protruding support on the vial of the instant claims (See Figure 2A), but still provides the same function – providing a pressure tight seal by ensuring that the vial is inserted properly into the cartridge. See column 7, lines 60-64 and column 10, lines 32-45 of Cargill. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant,) See MPEP 2144.04, Section IV, B -"Changes in Shape".

23. Applicant has also argued that *In re Dailey* does not apply. Applicant has argued that the small narrowed portion of Cargill below the frit does not provide the function of retaining the solid support and frit (Pages 43-44 of Arguments). The Examiner respectfully disagrees and directs Applicant to Figure 2A of Cargill which shows the frit (124) retained by the narrow portion (annular bead – 126) and the tapered bottom of the vial. See also column 8, lines 5-10 of Cargill which states "Lower portion 114 [of the vial] preferably also includes an annular bead 126 to retain frit 124 when it is pressed into place". The Examiner submits that in Cargill, the vial simply tapers at the bottom such that the vial is a different shape than the instant vial - but it still holds the frit in

place. The amount of tapering in Cargill is different and leads to a different vial shape, but again, the taper at the bottom provides support for the support and frit of Cargill.

24. Applicant has argued that the tapered feature is significant since the tapered feature is what makes a consistent compression and seal with the frit possible (pages 45-46 of Arguments). Applicant refers to the following passage from the Specification:

Present Specification that "[a] precision bored interior 630 holds the flit 620 in place and provides a consistent compression and seal with the flit 620. As a result of the precision bored interior 630, there is a consistent flow of reagent solution through each vial during both the dispensing and purging processes."

[Present Specification, page 14, lines 3-6]. See Arguments, page 45.

The Examiner notes, however, that this passage has nothing to do with the taper of the vial and instead is directed simply to a bored interior. Applicant has also argued that the tapered configuration is key to producing a consistent flow. The Examiner again notes that "a consistent flow" has nothing to do with retaining the frit or support in the vial. The issue is whether the vial having a different shape can still retain the frit. In the case of Cargill, this is what the prior art shows – a vial having a different shape but still retaining the frit.

25. Applicant has also argued that the tapered configuration is significant in that it allows substantially the entire body of the vial to fit within the cartridge. Applicant refers to the Specification (Page 14, lines 7-9) on page 46 of Arguments:

"....that "[t]he exterior of each vial 181 also has a precise dimension around the support 660. This support 660 fits within the receiving hole 185 within the cartridge 170 and provides a pressure tight seal around each vial within the cartridge 170." [Present Specification, page 14, lines 7-9] In other words, **because the tapered configuration ensures that the vial gets increasingly narrower from top to bottom, it allows the support 660 to be specifically dimensioned to form an air-tight seal with the cartridge without any of the lower portions of the vial being too large to fit within the cartridge hole.**

The Examiner submits that Applicant's Arguments are beyond the scope of this passage. The passage from the Specification cited by Applicant does not cite the tapering shape as critical to vial insertion.

26. Applicant has argued Cargill does not have a support that has a precise dimension that provides a pressure tight seal around the vial when placed in a cartridge. Applicant has also argued that Cargill does not teach a direct fit (Pages 47-59 of Arguments). The Examiner directs Applicant to Paragraphs 17 and 18 of the Office Action mailed 09/18/09 which addresses this argument.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1773